K091157

510(K) Summary

This summary of 510(k) - safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Application date: 04/17/09

2. Submitter Information

Infopia Co.,Ltd.

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NOV 17 2009

3. U.S Agent/Contact Person

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Santa Fe Springs, CA 90670
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Email: agent.fda@gmail.com

4. Trade name: GLUCOLAB Auto-coding™ (IGM-0022)

5. Classification:

Class II

Glucose test system (21 CFR Part 862.1345, NBW/CGA)
Quality control material (assayed and unassayed) (21 CFR Part 862.1660, JJX)

6. The legally marketed (Unmodified) Device / Predicate

GLUCOLAB™ (K051285) Blood Glucose Monitoring System, Infopia co., Ltd.

7. Device Description

GLUCOLAB Auto-coding™ Blood Glucose Monitoring System is comprised of test meter, test strip and control solutions. GLUCOLAB Auto-coding™ Blood glucose test meter is substantially identical with the predicated device (GlucoLab™: K051285). The minor difference is that the GLUCOLAB Auto-coding™ test meter has auto-coding function, which GlucoLab ™ test meter does not have. GLUCOLAB Auto-coding™ test meter can recognize the code of the test strips automatically. This function is intended to decrease user's incorrect code matching.

GLUCOLAB Auto-coding™ blood glucose test strip is identical with the predicated device (GlucoLab™: K051285) except code recognition band at the back side of the strip. This code recognition band is for auto-coding function of GLUCOLAB Auto-coding™ test meter.

GLUCOLAB Auto-coding™ glucose control solutions are exactly same as GlucoLab™ control solutions.

8. Intended Use

The GLUCOLAB Auto-coding™ Diabetes Monitoring System is used for the quantitative measurement of glucose level in whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings, including physician's office laboratories and point of care sites . The GLUCOLAB Auto-coding™ System provides plasma equivalent results. The GLUCOLAB Auto-coding™ System is not intended to be used with neonatal blood samples. The GLUCOLAB Auto-coding™ System is for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip testing along with alternate site testing on the forearm, upper arm, palm, calf and thigh.

GLUCOLAB Auto-coding™ control is used with GLUCOLAB Auto-coding™ Brand System to check that the meter and test strips are working together as a system and that you are performing the test correctly. It is very important that you do control solution tests routinely to make sure you are getting accurate results.

Control Solutions are sold separately.

9. Comparison to the Cleared Device

The technological characteristics of the revised device (GLUCOLAB Auto-coding™) in comparison to the predicated devices (GlucoLab™). The modified device has the same technological characteristics as the current legally marketed predicated device, GlucoLab™ (K051285) by Infopia Co., Ltd.

10. Performance Data

Clinical: The clinical performance evaluation using the GLUCOLAB Auto-coding™ Blood Glucose Monitoring System components were conducted for purpose of validating the consumer use for the user and the professional accuracy. Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the GLUCOLAB Auto-coding™ Blood Glucose Monitoring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

11. Conclusion

The conclusion drawn from the clinical and nonclinical tests is that the GLUCOLAB Auto-coding™ Blood Glucose Monitoring System is as safe, as effective and performs as well as the legally marketed predicated device, the GlucoLab™(K051285).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Infopia CO., Ltd
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Santa Fe Springs, CA 90670

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

NOV 17 2009

Re: k091157
Trade/Device Name: GLUCOLAB Auto-coding Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: October 23, 2009
Received: October 27, 2009

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K091157

Device Name: GLUCOLAB Auto-coding™ Blood Glucose Monitoring System

Indication For Use:

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Control Solutions are sold separately.

Prescription Use __√__	And/Or	Over the Counter Use __√__
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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